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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,277	03/12/2004	Thomas M. McGrath	3176	1331
26822	7590	06/02/2006		
WALTER A. HACKLER 2372 S.E. BRISTOL, SUITE B NEWPORT BEACH, CA 92660-0755			EXAMINER AN, SANG WOOK	
			ART UNIT 1732	PAPER NUMBER

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/800,277

Applicant(s)

MCGRATH ET AL.

Examiner

Sang W. An

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/12/2004</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The step of adding the ultraviolet blocker is performed with the final pellet mixture, not with the first pellet mixture alone. The last two limitations of the claim reads, "ultraviolet blocker and first pellet mixture." The examiner suggests amending the claim to read, "ultraviolet blocker and final pellet mixture."

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forte et al (20010048988) in view of Stier (20030091600) and supported by Cook et al (6465062).

Regarding claim 12, Forte et al teach a method for storing a pharmaceutical formulation (abstract), said method comprising the steps of: forming a bottle of a resin comprising polypropylene (par 0012) with a first set of dyestuffs present in said bottle in an amount sufficient to absorb visible and ultraviolet wavelengths less than about 420 nm, an ultraviolet blocking agent to absorb ultraviolet wavelengths less than about 312 nm (par 0016; to be considered a UV absorber, it must absorb wavelengths below about 312 nm), a second set of dyestuffs present in said bottle in an amount sufficient to absorb visible wavelengths greater than about 500 nm, the first and second dyestuffs sets allowing transmission of visible blue wavelengths (par 0017) for enabling visual inspection of the product contained in said bottle and providing a product identifying color to said bottle, disposing the pharmaceutical formulation in said bottle; and sealing said bottle (abstract). Examiner notes that in order to have a blue tint, the colorants must be absorbing most visible wavelengths greater than 500 nm and less than 420 nm, because wavelengths between 420-500 nm transmit blue color producing the blue tint and therefore inherently taught.

Forte et al do not teach that the pharmaceutical formulation is chlorine dioxide and do not explicitly teach first and second set of dyestuff.

However, Stier teaches that chlorine dioxide is used as a pharmaceutical formulation such mouthwashes and rinses (par 0044). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to store pharmaceutical formulation comprising chlorine dioxide in Forte's pharmaceutical container. One would have been motivated to do so because Forte's method produces a container that is suitable for storing pharmaceutical formulations such as chlorine dioxide.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time of invention to use first and second set of dyestuff or any other combination to produce blue tinting that is visible when transmitting wavelengths between 420-500 nm, in order to fulfill the wavelength requirements based on the intended end result of the container such as blue tint. One skilled in the art would know that two or more dyestuff could be used to absorb certain wavelengths while transmitting others as desired. The rationale for this rejection relies on sound scientific principle, In re Soli, 317 F.2d 941, 137 USPQ 797 (CCPA 1963). Cook et al give the support for above. Cook et al teach that the amount of yellow or black dye included in multi-layered wall material can be varied depending upon the desired light barrier characteristics for a container produced (col 6 lines 40-55). Therefore it would have been obvious to one having ordinary skill in the art at the time of invention to modify Forte's method of making pharmaceutical containers to include first set of dyestuffs absorbing at less than about 420 nm and second set of dyestuff absorbing at greater than about 500 nm. One would have been

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motivated to do so in order to create a blue tint as taught by Forte et al which is visibly transmitted between 420-500 nm.

Regarding claims 13, Forte et al teach adding ultraviolet blocker (par 0016; to be considered a UV absorber, it must absorb wavelengths below about 312 nm). They also teach that other similar polypropylenes, LDPEs, MDPEs, HDPEs having similar properties and capable of forming blow molded bottles, alone or in combination may be used in accordance with the invention (par 0014) but do not explicitly teach first, second, and third polypropylene resin pellets where the second pellet contains a set of dyestuff absorbing wavelength less than about 420 nm and third pellet contain dyestuff absorbing at greater than about 500 nm; forming premixture between first and second pellets; and forming final pellet mixture with the premixture and third pellets.

However, these steps seem to be obvious variations of Forte et al's teaching that any combination of the above mentioned polypropylenes can be used to produce the final product. For example, one having ordinary skill in the art may decide to mix different proportions of LDPE, MDPE, and HDPE in order to create a final product with desired material property. There appears to be lack of criticality in the applicant's claimed method/combination of providing the three resin pellets and the order in which they are mixed together. As to the limitations concerning dyestuff absorbing at less than 420 nm and greater than 500 nm, one having ordinary skill in the art would know that one or more dyestuff could be added to any one of the three resin pellets in any combination as long as the final outcome, after mixing all three sets of pellets, produces a desired light barrier characteristics such as blue tint. As set forth in In re Burhans,

154 F.2d 690, 69 USPQ 330 (CCPA 1946), selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results. The applicants order of mixing the pellets appear to be absent of new or unexpected results.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the teachings of using similar polypropylenes, LDPEs, MDPEs, HDPEs having similar properties and capable of forming blow molded bottles, alone or in combination as taught by Forte et al. One would have been motivated to do so in order to produce a final container with desired material properties such as stiffness.

As to the dyestuff in the second and third resin pellets absorbing at less than 420 nm and greater than 500 nm respectively, it would have been obvious to one of ordinary skill in the art at the time of invention to use first and second set of dyestuff or any other combination to produce blue tinting that is visible when transmitting wavelengths between 420-500 nm, in order to fulfill the wavelength requirements based on the intended end result of the container such as blue tint. Further explaining, one skilled in the art would know that two or more dyestuff could be used to absorb certain wavelengths while transmitting others as desired. The rationale for this rejection relies on sound scientific principle in the art, In re Soli, 317 F.2d 941, 137 USPQ 797 (CCPA 1963). Cook et al give the support for above. Cook et al teach that the amount of yellow or black dye included in multi-layered wall material can be varied depending upon the desired light barrier characteristics for a container produced (col 6 lines 40-55). Therefore it would have been obvious to one having ordinary skill in the art at the time of invention to modify Forte's method of making pharmaceutical containers to

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include first set of dyestuffs absorbing at less than about 420 nm and second set of dyestuff absorbing at greater than about 500 nm added to the pellets in any combination. One would have been motivated to do so in order to create a blue tint, as taught by Forte et al, which is visibly transmitted between 420-500 nm.

5. Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forte et al (20010048988) in view of Stier (20030091600) and supported by Cook et al (6465062) as applied to claims 12 and 13 further in view of Arakawa et al (6039893). The teachings of Forte et al (20010048988) in view of Stier (20030091600) and supported by Cook et al are applied as above for claims 12 and 13.

Regarding claim 14, Forte et al do not teach providing the second resin pellets comprising blue dye and purple dye pellets. However, Arakawa et al teach that bluish-purple and blue dye show absorption bands from 550 nm to 620 nm (col 1 lines 45-47). Therefore it would have been obvious to one having ordinary skill in the art at the time of invention to modify Forte's method of making pharmaceutical container to have the blue and purple dye. One would have been motivated to do so in order to create the blue tint taught by Forte et al which must absorb light at wavelengths greater than 500 nm and less than 420 nm.

Regarding claims 15 and 16, Forte et al do not explicitly teach the ratios disclosed. However, one of ordinary skill in the art would know that mixing various proportions of dyestuff would produce a different end result such as light barrier property. Cook et al give the support for above. Cook et al teach that the amount of yellow or black dye included in multi-layered wall material can be varied depending



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upon the desired light barrier characteristics for a container produced (col 6 lines 40-55). This establishes that the proportions of dyestuff is a result effective variable.

Therefore the examiner notes that discovering the optimum value of a result effective variable involves only routine skill in the art. "In re Boesch," 617F.2d 272,205 USPQ215 (COPA 1980). Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to determine the claimed ratios in claims 15 and 16 in order to produce a blue tint (a result effective variable) for the final product

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sang W. An whose telephone number is (571) 272-1997. The examiner can normally be reached on Mon-Fri 9 AM - 6:30 PM.

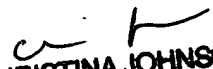
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina A. Johnson can be reached on (571)272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sang Wook An  
Patent Examiner  
Art Unit 1732  
May 23, 2006



  
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PRIMARY EXAMINER  
5/21/06